



STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

TO: Chief Procurement Officer
FROM: Health/State Laboratories Division
Name of Requesting Department

Pursuant to HRS §103D-306 and HAR chapter 3-122, Subchapter 9, the Department requests sole source approval to purchase the following:

<p>1. Describe the goods, services, or construction to be procured.</p> <p>Roche MagNapture Extraction kits and consumables, FASTART DNA Master Hybridization probes, Glycogen, Proteinase K, Rnase inhibitor, and microplates and sealers. Please refer to attachment for Catalog numbers.</p>	
<p>2. Vendor/Contractor/Service Provider Name:</p> <p>Roche Diagnostics Corporation, 9115 Hague Road, Indianapolis, IN 46250</p>	<p>3. Amount of Request:</p> <p>\$50,000 Est.</p>
<p>4. Term of contract (shall not exceed 12 months), if applicable:</p> <p>From: 12/1/2016 To: 11/30/2017</p>	<p>5. Prior SPO-001, Sole Source (SS) No.:</p> <p>SS16-016B</p>
<p>6. Describe in detail the following:</p> <p>a. The unique features, characteristics, or capabilities of the goods, service or construction.</p> <p>The Fastart probes and other PCR assay reagents (glycogen, Proteinase K, Rnase inhibitor) were selected by the CDC and have passed the performance characteristics set by the CDC for the extraction of biothreat agents. Our laboratory has demonstrated that these PCR reagents and kits have performed well and have demonstrated good sensitivity for detection as expected. MagNapture extraction kits and consumables are used exclusively in the performance of High-Throughput, semi-automated nucleic acid extraction of clinical specimens, tissues, environmental and food specimens using the MagNapture LC system. In particular, MagNaPure extraction products are used exclusively for Zika testing.</p> <p>b. How the unique features, characteristics or capabilities of the goods, service or construction are essential for the department</p> <p>Molecular testing of clinical specimens (human and animal), environmental, food and drinking water samples have been developed by National Reference Laboratories such as the CDC, NVSL and FDA for Public Health Laboratories. These molecular methods, such as the real-time (rti) PCR provide a rapid way to screen for biothreat agents and emerging threats such as Ebola virus, MERS-CoV, Zika virus, West Nile Virus (WNV), Chikungunya and dengue viruses, Human, Avian and Swine Flu virus, norovirus, B. pertussis/parapertussis, and a number of emerging pathogens such as Zika virus infections. The MagNaPure extraction protocols provide a High-Throughput (HT) extraction which is critical as the State Lab braces for high volume of testing for the detection of Zika virus especially among symptomatic and asymptomatic pregnant women. By increasing the number of specimens that we can process, we are able to complete testing in a timely manner. More importantly, a laboratory detection of Zika virus in pregnant women is a critical and moral dilemma because a serious health outcome like microcephaly has been associated with the virus.</p>	

7. Describe the efforts and results in determining that this is the only vendor/contractor/service provider who can provide the goods, services or construction.

Roche is the sole source of the reagents and kits described in Section 1. The methods that we use in testing for specific biothreat agents and toxins are standardized by the Center for Disease Control (CDC) Laboratory Response Network (LRN) for member LRN Reference laboratories, such as the Hawaii State Lab Division. Specifically, the FDA has approved the Emergency Use Authorization (EUA) of the Trioplex rti RT-PCR assay for the detection of Zika virus, dengue virus and chikungunya viruses in serum, urine and whole blood. With this EUA, the MagnaPure kits are authorized for use in this Trioplex Assay. Finally, our ability to maintain our status as LRN Reference Lab of good standing, depend on our ability to pass Proficiency Testing (PT) challenges using standardized reagents and kits specified in Section 1. Passing PTs are essential

8. Alternate source. Describe the other possible sources for the goods, services, or construction that were investigated but did not meet the department's needs.

There are no alternate source.

9. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required.)

*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	E-mail Address
Rebecca H. Sciulli	HI State Lab Division	808-453-5993	rebecca.sciulli@doh.hawaii.gov

Department shall ensure adherence to applicable administrative and statutory requirements, including HAR chapter 3-122, Subchapter 15, Cost or Pricing Data if required.

All requirements/approvals and internal controls for this expenditure is the responsibility of the department.

I certify that the information provided is to the best of my knowledge, true and correct.


Department Head Signature

OCT 13 2016

Date

For Chief Procurement Officer Use Only

Date Notice Posted: 10/14/2016

Submit written objection to this notice to issue a sole source contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

Approval is granted for the period 12/01/2016 to 11/30/2017 and is based on the Department's representation that the supplies and test kits are essential for their work and can only be obtained through Roche Diagnostics. This approval is for the solicitation process only, HRS Section 103D-310(c) and HAR Section 3-122-112 shall apply (i.e. vendor is required to provide proof of compliance and may use the Hawaii Compliance Express) and the award is required to be posted on the Awards Reporting System. Copies of the compliance and the awards posting are required to be documented in the procurement/contract file.

Department is also reminded that sole source contracts in excess of \$100,000 require certified cost or pricing data pursuant to HAR Chapter 3-122, subchapter 15 and are required to be documented in the procurement/contract file.

If there are any questions, please contact Kevin Takaesu at 586-0568 or kevin.s.takaesu@hawaii.gov.

☒ Approved

☐ Disapproved

☐ No Action Required


Chief Procurement Officer Signature

10/28/16
Date



October 3, 2016

Hawaii Dept. of Health
2725 Waimano Home Road, 2nd Floor
Pearl City, HI 96782-1401

Roche as Sole Source for MagNA Pure Products

To whom it may concern,

Roche is the sole manufacturer and distributor of MagNA Pure branded products, including the MagNA Pure 96 and MagNA Pure LC 2.0 Instruments, Reagents, Consumables, and Accessories.

If you have any questions, or would like additional information, please contact your local account manager or myself.

Regards,

A handwritten signature in black ink, appearing to read "DL", with a large, stylized loop at the end.

David Lahm
Roche Diagnostics Corporation
Molecular Diagnostics - Marketing Manager, Instrumentation
Cell 317-270-3434



Roche Items

MagNA Pure LC RNA Kit, High Performance. Cat# 03542394001
FastStart DNA Master Hybridization Kit. Cat# 3003248001
LightCycler FastStart DNA Master Plus Hybridization Kit. Cat# 03515575001
Uracil-N-glycosylase Cat # 11775367001
MagNA Pure LC RNA Isolation Kit III. Cat# 3330591001
MagNA Lyser Green Beads. Cat# 03358941001
Proteinase K, Recombinant PCR Grade. Cat# 03115879001
Swab Extraction Tube System (SETS). Cat# 03315568001
MagNA Pure LC Medium 20 Reagent Tubs. Cat# 03045501001
MAGNA Pure LC Processing Cartridges. Cat# 030004147001
MagNA Pure LC Large Reagent Tubs. Cat# 03004040001
MagNA Pure LC Tub Lids-Small/Medium. Cat# 03004082001
MAGNA Pure LC Tub Lid Seals. Cat# 03004104001
MAGNA Pure LC Reaction Tips, Small. Cat# 03004180001
MAGNA Pure LC Reaction Tips, Large. Cat# 03004171001
MagNA Pure LC Sample Cartridges. Cat #03004112001
MAGNA Pure LC Cap Seals. Cat# 03118827001
MAGNA Pure LC Reagent Tubs, Small. Cat# 03004066001
MagNA Pure LC Reagent Tubs, Medium 30. Cat# 03045501001
MagNA Pure LC Tub Lids, Large. Cat# 03004074001
MagNA Pure LC Tip Stands. Cat# 03004155001
MAGNA Pure LC Waste Bottles. Cat# 03004198001